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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,367	05/11/2001	Francis Michon	1758-4050	5710

7590 04/16/2002  
MORGAN & FINNEGAN, L.L.P.  
345 Park Avenue  
New York, NY 10154-0053

EXAMINER
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DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/16/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/853,367

Applicant(s)

Michon et al.

Examiner  
S. Devi, Ph.D.

Art Unit  
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Sep 10, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☒ Claims 1-33 are subject to restriction and/or election requirement.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

**Restriction/Election**

- 1) Claims 1-33 are under prosecution.
- 2) **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 3) Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-18 and 29, drawn to an immunogenic conjugate molecule comprising hyaluronic acid covalently bound to a polypeptide carrier and a vaccine comprising the same, classified in class 424, subclass 197.11.
  - II. Claims 19 and 20, drawn to a method of preparing a hyaluronic acid-polypeptide conjugate by reductive amination, classified in class 536, subclass 123.1.
  - III. Claims 21-24 and 33, drawn to a purified antibody to the conjugate molecule comprising hyaluronic acid covalently bound to a polypeptide carrier and an immunoassay kit comprising the same, classified in class 530, subclass 387.5.
  - IV. Claims 25-28, drawn to a method of producing an antibody response by administering to a mammal a low molecular weight hyaluronic acid covalently bound to a polypeptide carrier, classified in class 436, subclass 547.
  - V. Claims 30-33, drawn to a method of inhibiting streptococcal infection and progression of infection caused by HA-containing bacteria in a mammal, classified in class 424, subclass 244.1.
- 4) Inventions I through V are distinct from one another. Inventions I and III are drawn to two distinct products, a hyaluronic acid-polypeptide conjugate and an antibody, which differ from one another structurally, functionally, immunologically and/or biologically.

5) Invention I is related to inventions IV and V as product and processes of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the conjugate of invention I can be used in a materially different process, for example, as a source of coating hyaluronate antigen in an *in vitro* diagnostic assay. The method of eliciting an antibody response of invention IV can be produced by using a product materially different from the conjugate of invention I, for example, a hyaluronic acid-containing microorganism admixed in a strong adjuvant. Similarly, the method of inhibiting streptococcal infection of invention V can be produced by using a product materially different from the conjugate of invention I, for example, a non-hyaluronic acid product, such as a streptococcal polypeptide.

6) Inventions I and II are related as product and process of making the product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case, the conjugate of invention I can be made by a process materially different from the process of inventions II using one of art-known processes that does not involve reductive amination, for example, carbodiimide coupling.

Because these inventions are distinct for the reasons given and have acquired a separate status in the art as shown by their different classifications/subclassifications and divergent subject matter, restriction for examination purposes as indicated is proper.

7) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).

8) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition

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under C.F.R 1.48(b) and by the fee required under 37 C.F.R 1.17(h).

9) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
S. DEVI, PH.D.  
PRIMARY EXAMINER

April 2002



# RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

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ART UNIT: 1645

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